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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,538	10/12/2001	Michael P. McLeod	7504-80241	1515

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,538

Applicant(s)

MCLEOD ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 13 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In lines 1-2 of claims 13, “the acquisition unit” lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. Claims 1-4 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rohde (US 5876351). Rohde discloses a portable modular ECG monitoring device with an LCD display (20) with sufficient resolution to display waveforms. The sensed cardiac signals are inherently intrinsic beats or pace/ shock beats as these signal are all sensed when monitoring an ECG (abstract; figure 2(a); col. 4 @ 46-67; col. 5 @ 18-21 and 41-43; col. 6 @ 51-54).

The Applicant’s arguments have been fully considered but they are not convincing.

The Applicant asserts Rohde does not disclose the elements of the claimed invention. The Examiner disagrees. The cartridge (12) is read as the acquisition unit, the leads (14) are read as the relatively short lead wires, the platform (10) is read as the processing element, and the connector (17) with contacts (figure 2 (b) – 17) provides insulated wires that connect the units, read as the connector cable (figures 1 and 2b).

The Applicant asserts the leads of the Rohde invention are “relatively long” leads. The Applicant also asserts one skilled in the art would understand “relatively short leads would allow the acquisition element to reside on the chest of the patient as shown in figure 1”. The Examiner disagrees with both statements. The leads disclosed by Rohde are used in typical ECG monitoring applications, such leads understood to be “relatively short” in comparison to leads used during ECG stress tests where patient movement and distance between the patient and the recording equipment require relatively long ECG leads. Because ECG leads are used in such a wide variety of applications, the limitations of “relatively short” has little meaning and would not be understood by one skilled in the art as “allowing the acquisition element to reside on the chest of the patient as shown in figure 1”. It is noted “relatively long” and “relatively short” are very general subjective descriptive terms, and more precision is needed to convey the uniqueness of the length of the leads of the instant invention.

In response to the Applicant's arguments that the reference fails to show certain features of the Applicant's invention, it is noted that the features upon which the Applicant relies (i.e., the functionality of the instant invention, compliance with applicable medical safety and performance standards, placement of the device on the patient's chest, reduced EMI, and relatively short leads as shown in figure 1) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant argues that the instant invention is unique because it is an acquisition unit and a processing element versus the unitary device taught by Rohde. Relative to components of an article and the integration of these components, it has been established that forming into a

single piece an article which has formally been formed into multiple pieces involves only routine skill in the art and hence does not create a unique or novel invention (*Howard v. Detroit Stove Works*, 150 US. 164(1893)).

Claim Rejections - 35 USC § 103

3. Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) in view of Skelton et al. (US 6292692). As discussed in paragraph 2 of this action, Rohde discloses the claimed invention except for the screen being a touch screen interface.

Skelton et al. teach communications interface using a touch screen for the purpose of making input selection known to a controller/ microprocessor. Absent any teachings of criticality of unexpected results, merely changing the input means from a joystick and control buttons to a touch screen interface would be an obvious design choice.

4. Claims 6-12 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) in view of Rockwell et al. (US 6141584). As discussed in paragraph 2 of this action, Rohde discloses the claimed invention except for: a read only memory card (claims 6 and 7), wireless communication using an infrared transceiver (claim 8) or a radio frequency transceiver (claim 9), an audio recording unit (claim 10), signal conditioning circuits (claim 11), a “baseline sway filter” (claim 12) and signal analysis and interpretation (claim 14).

As to a memory card, Rockwell et al. teaches data storage using a read only memory card for the purpose of recording the ECG and audio data in memory. It would have been obvious to

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one having ordinary skill in the art at the time of the invention to have used the read only memory card in the Rohde system in order to provide a mechanism enabling the collected data to be reviewed and analyzed at a future time (col. 11 @ 3-16).

As to wireless communication, Rockwell et al. teach wireless communication using infrared and radio frequency communication signals for the purpose of conveying information to remote locations. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used infrared and radio frequency signals in the Rohde system in order to enable sharing of information and report generation to optimize the patient's treatment (col. 5 @ 2-17).

As to an audio unit, Rockwell et al. teach event recording using an audio unit for the purpose of documenting events associated with patient interaction and care. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an audio unit in the Rohde system in order to provide a more comprehensive understanding of the patient's condition and the treatment afforded the patient so the events are accurately reconstructed (col. 10 @ 1-9)

As to signal conditioning and filtering, Rockwell et al. teach signal conditioning using an amplifier, filter (read as a baseline sway filter), A /D converter for the purpose of optimizing the quality of the signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used signal conditioning including baseline sway filtering in the Rohde system in order to eliminate signal artifact, making the cardiac signals distinct so they can be more easily interpreted (col. 10 @ 46-49).

As to signal analysis, Rockwell et al. teach cardiac signal evaluation using signal analysis for the purpose of detecting the cardiac rhythm of the heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used signal analysis in the Rohde system in order to alert the user to cardiac condition, so conditions such as ventricular tachycardia requiring immediate medical attention can be identified and treated (col. 10 @ 49-51).

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist at telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
5/16/04

Angela D. Sykes

ANGELA D. SYKES
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